

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
GLASS VIAL**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Substances:

| | |
|---|--------|
| Procaine Hydrochloride | 50mg |
| Adrenaline (Epinephrine) (as Adrenaline Tartrate) | 0.02mg |

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

By subcutaneous injection.

5. WITHDRAWAL PERIODS

Meat and offal: Zero days

Milk: Zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

9. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Substances:

| | |
|---|--------|
| Procaine Hydrochloride | 50mg |
| Adrenaline (Epinephrine) (as Adrenaline Tartrate) | 0.02mg |

3. PACKAGE SIZE

100ml

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

The product should be administered by subcutaneous injection as follows:

Cattle: 2-5 ml.

Avoid excessive broaching.

Do not exceed the recommended dose.

7. WITHDRAWAL PERIOD

Meat and offal: Zero days

Milk: Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

Keep the container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 02000/4243

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Adrenacaine Solution for Injection for Cattle

2. Composition

Each ml contains:

Active substance:

| | |
|---|--------|
| Procaine Hydrochloride | 50mg |
| Adrenaline (Epinephrine) (as Adrenaline Tartrate) | 0.02mg |

| | |
|---|-------|
| Excipients: Chlorocresol (as preservative) | 1.0mg |
| Sodium Metabisulphite E223 (as antioxidant) | 1.0mg |

A clear colourless solution

3. Target Species

Cattle

4. Indications for use

The veterinary medicinal product is indicated for use in minor surgical procedures, particularly dehorning and disbudding in cattle.

5. Contraindications

Do not administer by intravenous, intra-articular or epidural injection.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special Warnings

Special precautions for safe use in the target species:

Care should be taken not to inject the product intravascularly.'

Special precautions to be taken by the person administering the veterinary medicinal product:

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician. Immediately wash off any splashes to the eyes or skin with copious amounts of water.

Seek medical attention if irritation occurs.

Wash hands after use.

Pregnancy and lactation:

The product can be administered at any stage of pregnancy or lactation

Interaction with other medicinal products and other forms of interaction:

Procaine may inhibit the action of sulphonamides and their concurrent administration should be avoided.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose:

The product is well tolerated at doses up to 3 times the recommended dose for cattle.

Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects. If systemic toxicity occurs, as a result of inadvertent intravascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

By subcutaneous injection.

Cattle: 2 to 5 ml

9. Advice on correct administration

Avoid excessive broaching of the closure.

Do not exceed the recommended dose.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

10. Withdrawal periods

Meat and offal: Zero days

Milk: Zero hours

11. Special storage precautions

Do not store above 25°C.

Protect from light.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

Keep the container in the outer carton.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 02000/4243

100 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16.Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

15. Other information

POM-V

Gavin Hall
Approved: 03 April 2025